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## REMARKS

The present amendment is submitted in response to the Office Action mailed July 13, 2006. In that Office Action, the Examiner rejected claim 2 under 35 U.S.C. § 102(b), and rejected claims 1 and 3-9 under 35 U.S.C. § 103. The following Remarks are intended to address each of these matters. In addition, new claims 10-23 have been added. In view of the foregoing amendments and subsequent remarks, reconsideration and withdrawal of the Examiner's claim rejections are requested.

## 1. Claim Rejections – 35 U.S.C. § 103

Claims 1 and 3-9 were rejected under 35 U.S.C. § 103 for obviousness over the Simpson et al. patent in view one or more of the following: USP 5,728,062 to Preissman et al., USP 6,102,929 to Conway et al., and US 2002/0026217 to Baker et al. Applicant requests reconsideration and withdrawal of the Examiner's rejections.

In regard to claim 1, neither Simpson et al., Preissman et al., Conway et al., nor Baker et al., separately or in combination, mention, consider, describe, teach or suggest a device which regulates or monitors the pressure in the isolated region of the vessel between two balloons. Claim 1, on the other hand, recites a catheter system that includes:

... a pressure monitoring port located proximally of the second expandable occlusion device and open to said isolated interior segment between said first and second occlusion devices to monitor the pressure within said isolated interior segment.

Similarly, new claim 13 recites a catheter system that includes:

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a pressure regulator coupled to the second catheter and configured to regulate the pressure of an agent infused into said isolated interior segment between said first and second occlusion devices.

The Examiner refers to the Conway et al patent for the teaching of a catheter system utilizing a pressure regulator and pressure monitoring port to regulate the pressure in occlusion devices (e.g., balloons). However, even if there were a basis or grounds by which a person of skill in the art would have been motivated to combine the Simpson et al. and Preissman et al. patents with Conway et al, such combination would merely result, as indicated by the Examiner (pg. 4, section 3), in a catheter system with a pressure regulator configured to regulate the pressure of the two occlusion devices of Simpson. Because this combination fails to disclose each of the elements of the claims, a prima facie case of obviousness can not be established using these references.

Further, a prima facie case of obviousness can not be made with these references because there simply is no teaching available, either from the references or elsewhere, that would supply the motivation to make the necessary modifications to the references to meet the claim limitations. Such modifications would only be obvious through the inappropriate use of hindsight and reliance on the teachings of the subject claims. Accordingly, Applicants submit that claims 1 and 13, and 3-12 and 22 and 14-21 and 23 by virtue of their dependence on claims 1 and 13, respectively, meet the requirements for patentability.

## 2. <u>Claim Rejections – 35 U.S.C. § 102</u>

Claim 2 was rejected under 35 U.S.C. § 102(b) as being anticipated by Simpson et al. (US 6,126,635). Applicant requests reconsideration and withdrawal of this rejection as well. Simpson

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does not meet all of the limitations of this claim. Specifically, claim 2 recites a catheter system that includes "a catheter and a guide wire," in which the guide wire has:

a second expandable occlusion device associated therewith and being adapted to expand said second occlusion device distally of the first occlusion device on the first catheter.

Simpson does not teach or discuss a guidewire having an expandable occlusion device. As the Examiner and one skilled in the art are likely well aware, a catheter is not a guide wire. A guide wire by its very nature is physically different from a catheter and will allow the claimed device to extend into and treat vessel regions with smaller lumens. Simpson's only discussion of a guide wire makes this distinction clear. In connection with the embodiment shown in FIG. 10, Simpson discusses the use of a <u>conventional</u> guide wire (156) that is slidably received within an infusion lumen (138) of the inner catheter (112). Simpson simply does not disclose, teach, or suggest a guide wire having "an expandable occlusion device associated therewith." No occlusion device whatsoever is shown associated with the conventional guide wire disclosed and shown in FIG. 10 of Simpson.

The Examiner, however, attempts to rely on a guiding catheter 12 shown in FIG. 1 to meet this limitation. In the Office Action, the Examiner improperly refers to the catheter (12) shown in FIG. 1 of the Simpson patent as a "catheter/guidewire." But nowhere does the Simpson patent state that the catheter 12 can or should function as a guidewire in the described device. Instead, the Simpson patent describes the use of a "guiding catheter" that can be used to properly locate the catheter system, (see Col. 6, Il. 24-31), thereby avoiding the need for a guide wire and teaching away from the use of a guide wire. Thus, there is no basis for characterizing the inner catheter 12 of the Simpson et al. device as a "guide wire."

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Furthermore, Simpson focuses on the cleaning of debris in a blood vessel and bypass grafts within an isolated chamber formed by distal and proximal balloons to avoid the creation of an embolism. This, along with the fact that Simpson describes the use of a guiding catheter and the use of a conventional guide wire, suggests that the lumens Simpson is dealing with are relatively large and, thus, Simpson teaches away from the use of a guide wire having an expandable occlusion device to reach smaller lumens and isolate interior segments therein.

Accordingly, because the Simpson et al. patent does not disclose, teach, or suggest every limitation of claim 2, Applicants respectfully submit that claim 2 meets the requirements for patentability under 35 USC 102.

## CONCLUSION

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

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Respectfully submitted,

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